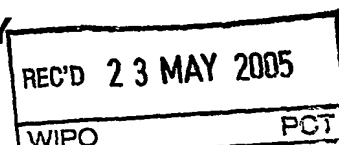



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference IS/BP6231880		FOR FURTHER ACTION See Form PCT/PEA/416	
International application No. PCT/GB2004/002770	International filing date (day/month/year) 28.06.2004	Priority date (day/month/year) 26.06.2003	
International Patent Classification (IPC) or national classification and IPC G01N27/48, G01N33/487			
Applicant CRANFIELD UNIVERSITY et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 2 sheets, as follows:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input checked="" type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 25.04.2005		Date of completion of this report 24.05.2005	
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Wilhelm, J Telephone No. +31 70 340-2633	



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/002770

Box No. 1 Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-9 filed with telefax on 25.04.2005

Drawings, Sheets

1/3-3/3 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
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Box No. II Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
- ☐ copy of the earlier application whose priority has been claimed (Rule 66.7(a)).
 - ☐ translation of the earlier application whose priority has been claimed (Rule 66.7(b)).
2. ☒ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rule 64.1). Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-9
	No: Claims	
Inventive step (IS)	Yes: Claims	1-9
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-9
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
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Re Item II

The feature of using Nafion-coated electrodes is not disclosed in the priority application GB0314944. The priority claim is therefore not valid.

Re Item V

1. The following document is referred to in this communication:
D1: EP-A-1143240 (FRAUNHOFER GES FORSCHUNG), 10 October 2001
(2001-10-10)

2. Clarity - Article 6 PCT

The claims are not supported by the description as required by Article 6 PCT, as their scope is broader than justified by the description. The present invention is directed towards voltammetric measurements on body fluids, using non-selective electrodes (see p. 9, l. 6-10). However, the scope of the claims also covers the use of enzyme electrodes for such measurements.

3. Independent Claim 1

Document D1 discloses a method for determining analytes (vitamin C) in a body fluid (urine), wherein a set of electrodes, comprising a non-selective working electrode (10), a reference electrode (15) and a counter electrode (5), is immersed in said fluid (35), a varying voltage (45) is applied to the working electrode (10), and the electrochemical outcome (55) is measured in order to obtain a signal related to the composition of the fluid (35).

Furthermore, it is suggested to apply the method also for detecting other analytes in other fluids, e.g. blood.

There is no suggestion in D1 to use Nafion-coated electrodes. This feature of claim 1

**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
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solves the problem of large macromolecules (proteins) interfering with the measured redox reaction.

The subject-matter of claim 1 is therefore new and inventive (Article 33 PCT).

4. Dependent claims

Claims 2-9 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Claims

1. A method for determining one or more analytes comprising glucose in a body fluid selected from interstitial fluid, whole blood, and plasma, comprising adding a sample of said fluid to an electrochemical cell containing a set of electrodes comprising a working electrode, a reference electrode and a counter electrode said electrodes being coated with a membrane of Nafion (perfluorosulfonic acid polymer); applying a varying potential to the working electrode thereby causing electrochemical redox reactions of said one or more analytes at the electrodes; and measuring the electrochemical outcome, thereby providing an output signal related to the composition of the fluid.

2. A method according to claim 1 wherein said fluid is interstitial fluid.

3. A method according to any preceding claim wherein the application of the varying potential is preceded by the application of one or more electrode cleaning pulses.

4. A method according to any preceding claim wherein the output signal is analysed to provide data about the concentration of one or more analytes.

5. A method according to claim 4 wherein the output signal is analysed to provide data about the concentration of plural analytes.

6. A method according to claim 4 or claim 5 wherein the analysis employs a multivariate calibration technique.

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7. A method according to any preceding claim wherein said sample of fluid is made more alkaline or acidic prior to determination.

8. A method according to any preceding claim wherein said
5 electrodes are film electrodes provided on a substrate.

9. A method according to any preceding claim wherein the electrodes are provided within a capillary element which is partly immersed in the fluid whereupon fluid rises into the element by capillary action to contact the electrodes.

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